

SPL Indexing

FDA Request for Comments



For the example, I've taken text from this website:

<http://www.benadryl.com/#/ChildrensProducts/Allergy-Liquid-4oz/>

Product Data Elements

- Children's BENADRYL[®] Allergy Liquid
 - Cherry flavor
 - Available in 4 oz (118 ml), 8 oz (236 ml)
 - Active ingredient: diphenhydramine HCl 12.5mg (in 5ml)
 - UNII = 8GTS82S83M
 - Route of administration = ORAL
 - Dosage form = Liquid

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This is indexing – the sponsor (or delegate) handles this...

Pharmacologic Class

- *...is a group of drugs that share scientifically documented properties. Pharmacologic class is defined on the basis of any one of the following three attributes of the drug:*
 - Mechanism of action (MOA) — Pharmacologic action at the receptor, membrane, or tissue level
 - Physiologic effect (PE) — Pharmacologic effect at the organ, system, or whole body level
 - Chemical structure (CS)

The FDA has already taken on the effort of indexing pharmacologic class. Their results can be found here:

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM199545.zip>

Pharmacologic Class

- Children's BENADRYL® Allergy Liquid
 - Purpose = ANTIHISTAMINE
- NDF-RT Concept
 - Histamine H1 Antagonists [MoA]
- NUI (NDF-RT ID#)
 - N0000000190
- FDA Established Pharmacologic Class
 - histamine-1 (H1) receptor antagonist

FDA is Asking...

- *For comments on how to index Indication...*
 - *How detailed?*
 - *What areas?*
 - *What types of products?*
 - *Etc.*

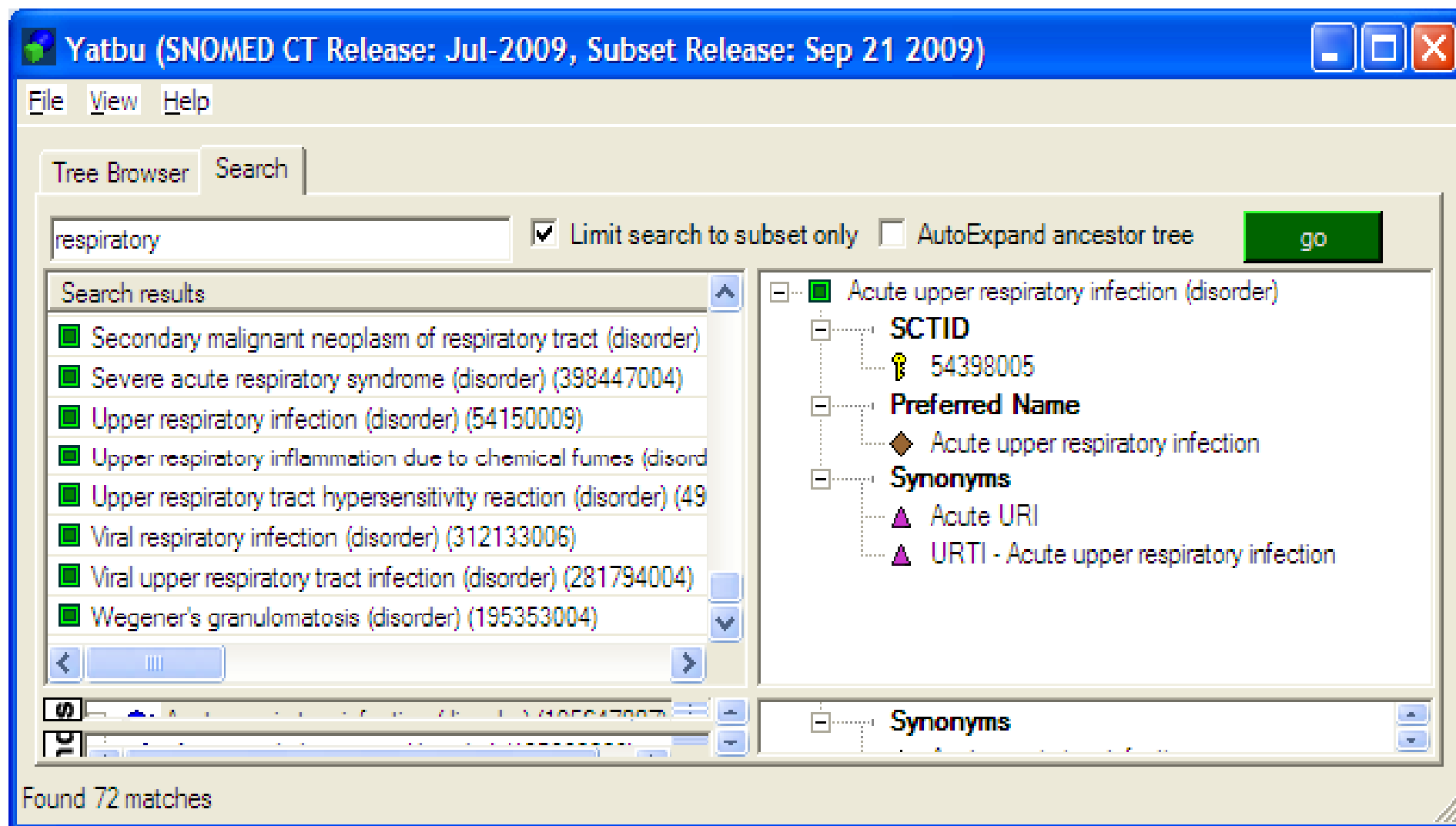
Indication

- [Indication Category](#) [for now “Medical Problem”]
- [Intent of Use](#) [treatment OR diagnosis OR prophylaxis]
- [Medical Condition](#)
- [Precondition Categories](#) [age, race, sex, medical problem]
- [Contributing Factor - General](#) [food OR food product]
- [Type of Consequence](#) [patient problem OR pharmacokinetic effect]
- [Pharmacokinetic Effect](#) [increases or decreases in drug levels, etc.]
- [Limitation of Use/Issues](#) [Use with Caution, Duration of Use, etc.]

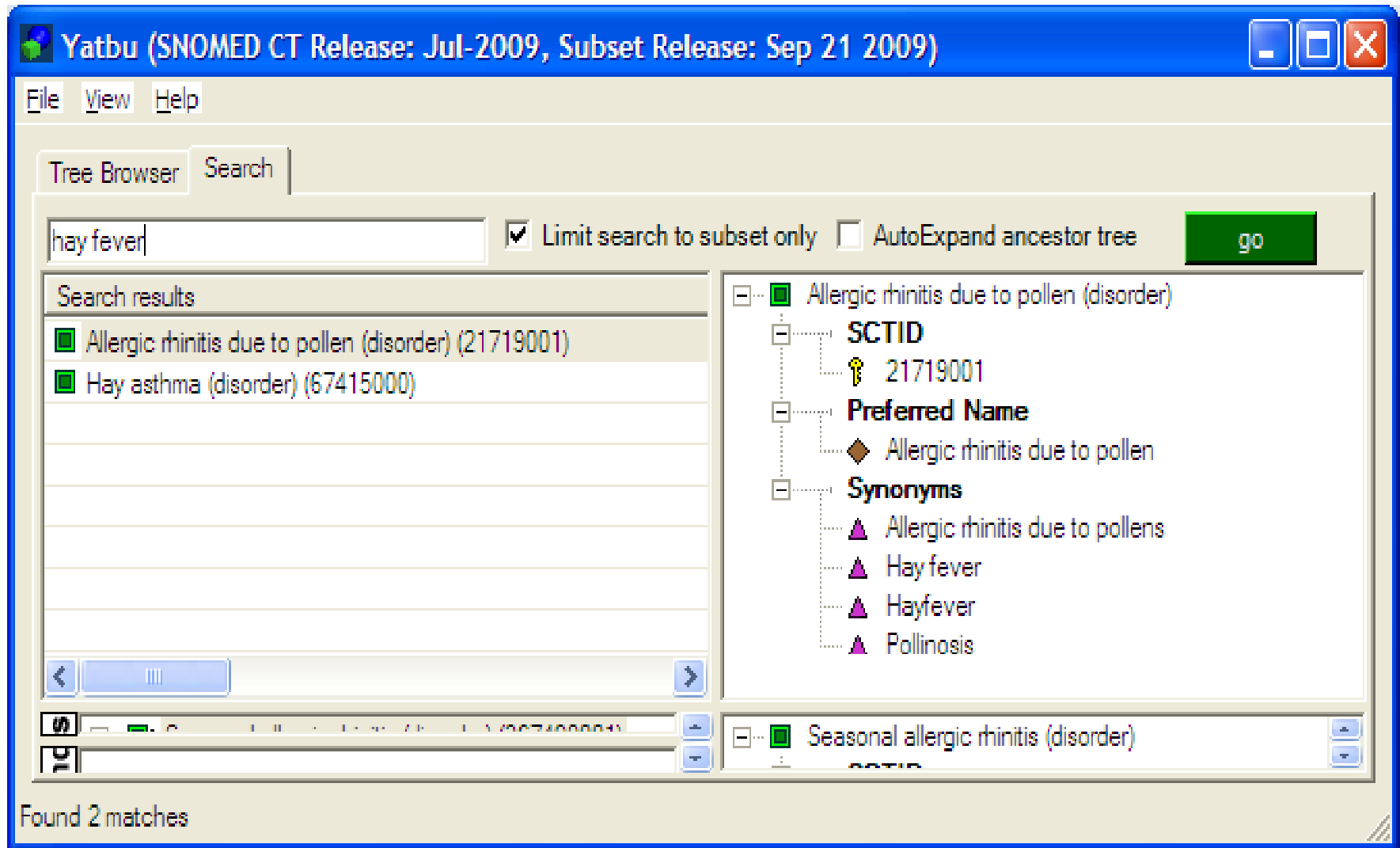
From the Label

- Uses
 - Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies
 - Runny nose
 - Sneezing
 - Itchy, watery eyes
 - Itching of the nose or throat

There are LOTS of medical condition terms...



- How Detailed should Indexing Be?



Indication

- [Indication Category](#) [“Medical Problem”]
- [Intent of Use](#) [treatment]
- [Medical Condition](#)
[allergic rhinitis due to pollen]

*Should the FDA index
symptoms? (itchy throat, runny nose)
Be very specific (hay fever only?) or more general (any
nasal allergy?)*

From the Label

- Warnings
 - Do not use
 - To make a child sleepy
 - With any other product containing diphenhydramine, even one used on skin
 - Ask a doctor before use if a child has
 - A breathing problem such as chronic bronchitis
 - Glaucoma
 - A sodium-restricted diet
 - Ask a doctor or pharmacist before use if the child is
 - Taking sedatives or tranquilizers
 - When using this product
 - Marked drowsiness may occur
 - Sedatives and tranquilizers may increase drowsiness
 - Excitability may occur, especially in children

Warnings / Precautions

- [Medical Condition](#)
- [Precondition Categories](#) [age, race, sex, medical problem]
- [Contributing Factor - General](#) [food OR food product]
- [Type of Consequence](#) [patient problem OR pharmacokinetic effect]
- [Pharmacokinetic Effect](#) [increases or decreases in drug levels, etc.]
- [Limitation of Use/Issues](#) [Use with Caution, Duration of Use, Contraindication, Interaction, etc.]

From the Label

- Do not use
 - To make a child sleepy
[Precondition Categories](#) [age]
[Limitation of Use/Issues](#) [Contraindication]
 - With any other product containing diphenhydramine, even one used on skin
[Type of Consequence](#) [patient problem?]
[Limitation of Use/Issues](#) [Interaction?]

*Should the FDA index
All limitations? Any limitations
Only observed interactions? Possible interactions?*

From the Label

- Directions

- Take every 4 to 6 hours
- Do not take more than 6 doses in 24 hours
- Children under 2 years:
 - Do not use
- Children 2 to 5 years:
 - Do not use unless directed by a doctor
- Children 6 to 11 years
 - 1 to 2 teaspoonfuls (12.5 mg to 25 mg)

Should the FDA indexing

*Be very specific (children of ages < 2, 3 – 5, 6 - 11?) or
more general (any children?)*

Categories of Terms

- [Indication Category](#) [for now “Medical Problem”]
- [Intent of Use](#) [treatment OR diagnosis OR prophylaxis]
- [Medical Condition](#)
- [Precondition Categories](#) [age, race, sex, medical problem]
- [Contributing Factor - General](#) [food OR food product]
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Lists available via:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>